Participant Information Sheet

vDOT

St. John’s Medical College Hospital, Bangalore

Study Title:
Technology for TB: Mobile phone based directly observed treatment for supporting adherence to antitubercular treatment in South India

Introduction and purpose of the study:
You are invited to be a part of a research study involving patients starting TB medications. The study will take place at the Chest disease clinic, St Johns hospital. Before you decide whether or not to volunteer for the study, you must understand the purpose of the study, how your participation may help you, any potential risks to you, and what is expected of you during the study.

In this study, we are trying to understand if mobile phone based video monitoring of treatment can help you take your TB medications better. We feel is it helpful for you to have a mobile phone which we can use to monitor your treatment via video instead of visiting the hospital to help you with taking medicines. We are trying to see if using the mobile phone to monitor your treatment will help you take all your medications within the required time period to ensure that you are cured.

In this study we are also trying to use some tests to see how you are doing once the medicines have been started. Some of these tests will help us identify easy and cheap methods to monitor if you have taken your medicines correctly even if you send us videos of taking your medicine.

What do I have to do in order to take part in this study?
If you decide to join this study, you will be put in one of two groups of persons as a matter of chance. In one group participants will be asked to video themselves while taking medicines using an application on their mobile phones this is called “video DOT”. These videos will have \ based on the schedule of the medicines prescribed.

The participants in the other group will receive the same care that is given to all patients with TB. For this, participants will have to come to the treatment center to be seen by the treatment supervisor while taking medicines, daily till the end of treatment, which is 6 months. However, the frequency of visits may vary based on treatment provider and the distance that you live from the hospital. Unlike the Video DOT group in this group participants will not have to video themselves while taking medicines nor will they receive counselling every month for medication adherence.

To ensure medication adherence as per the Indian TB program guidelines all patients participating in the study will receive adherence counselling.

You have a fifty-fifty chance of being in one of the two groups. However, the medicines and the tests done will be similar for all participants in both the groups. Also each person enrolling in this study will get a mobile phone free of charge and a fixed amount of money per month for keeping the sim card active and charging the internet. Persons in one group will get a mobile phone application which they will use to video record themselves while taking their medicine. They will also receive a reminder to take their medicine. Persons in the other group, will have to visit the hospital to be observed by the treatment provider while taking medicines.

TB Notification: As per government of India guidelines we are obligated to notify all patients with TB to the government. For this we will require to note down your phone number, residential address and AADHAAR number. This is primarily to ensure that you receive all the benefits that the government provides patients with TB and to ensure that the government has the correct information regarding the number of patients diagnosed, and treated through its TB program. This helps the government plan its services for patients with TB better. If you do not possess any of these details we will help you get them.
so that you can have the benefits from the government. While it is not obligatory to share all the details, some basic details will be required for notification.

**Follow-ups:** You will have to visit us monthly for the first 6 months and thereafter every 6 months for a year and a half. These visits are expected to take approximately one hour of your time. At these visits we will assess your health and request for necessary investigations such as some blood tests, urine tests and hair sample tests. Additionally, we may also request you to let us know of your experience (positive and negative experiences and concerns) with video DOT and counselling in detail so that we can improve upon the components of the intervention.

**Medications:** In this study you will be category one TB medicines that are routinely available at all DOT centres.

**Tests:** During this first visit, some tests will be done. These include blood tests that are haemoglobin tests, liver tests, kidney function tests, blood cell counts; sputum tests to check if the TB organism is in the sputum and to see if the medicines that you will be started on will kill the organism; blood and hair tests to see if the there is sufficient medicine in your body to kill the TB organism. After starting the TB medicines, you will be asked to do these tests in the second month, at the end of treatment and thereafter every 6 months for a period of 1 ½ years.

**Blood draws:** We will be collecting 5ml (=one teaspoon), of blood when you start the study and at 2 months 6 months, 12 months, 18 months and 24 months to study how you are responding to treatment. Blood collected after treatment completion will help us study the effect of tuberculosis and its treatment on your health over time.

In addition at week 8 (2 months after you have started your treatment) we will have to collect 5 ml (=one teaspoon) of blood 4 times, that is at 0, 2, 4 and 6hrs after you have taken your medicine. This will help us monitor the levels of TB medicines in your blood and compare them with the levels of TB medicines in your hair.

**How long is the study?** The study will go on for 2 years, this means you will have to visit us 6 monthly after you have completed your treatment for 2 years.

**What happens when my medicines are complete and I have been cured?**
After you finish 6 months of your treatment and are said to be cured you will have to visit us 3 times at 6 month intervals to test your sputum, you will be referred to the ART center in St Johns or closest center where you will continue to get your medicines and care free of cost.

**What happens if the tests indicate that category 1 medicines or the medicines that I have been taking will not kill the TB bacteria I have?**
In the event that the resistance test shows that you will not respond to or are not responding to the category 1 medicines that you are taking, then you will get category II treatment or medicine (stronger medicine) that will kill the bacteria. This medicine is also provided free of cost by the government at TB treatment centers. You may however choose to avail treatment provided at the TB treatment centers or treatment elsewhere.

**What are the risks in taking part in this study?** Drawing blood may cause some pain or bruising where the needle enters the body. This will be done by experienced staff, and the pain may be minimal.

**What are the benefits?** The study will help us find a new way to monitor how TB patients take their medicines. All the tests performed as part of the study will also be done free of cost. The information learned from this study will help researchers to understand how to improve future treatment of patients with Tuberculosis. Potential benefits to you of using the technology that will be studied, include taking medicines at your own convenience and less time spent travelling to and from the TB clinic.
All persons taking part in this study will get a free mobile phone with Rs.300/- worth fixed internet time and talk time per month and Rs. 200/ visit. You will be able to add more amounts and continue to talk longer, if needed. The medicines are also provided free of cost.

**Confidentiality:** All answers that you give and your blood test results will be kept private. All the videos that you upload will be kept private and will be seen only by the team treating you.

**Do I have to take part in this study?** It is not compulsory for you to take part in the study, and if you do decide to take part you may change your mind later at any time. You will continue to get the usual care from your doctor whether or not you decide to take part in this study.

**What do I do if I have questions or problems?**
If you have any concerns about the conduct of the study, you may contact
Rashmi Rodrigues, Assistant Professor, Community Health
Mobile Number: +91 9845389538
George D’Souza, Professor and Head, Chest Diseases
Mobile Number: +91 9449820962

For your rights as a study participant, you may contact

**Name of the IRB/EC:** Dr. Jayanthi Savio, Member Secretary
Institutional Ethics Committee,
St. John’s National Academy of Health Sciences,
Address: Bangalore 560034, Karnataka, India.

**Telephone Number:** Ph: +91-80-49466346

Thank you for taking the time to consider this study.

If you wish to take part in it, please sign the attached consent form.

This information sheet is for you to keep.
**CONSENT FORM**

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<thead>
<tr>
<th>Name of the Participant</th>
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**Study Title**  
Technology for TB: Mobile phone based directly observed treatment for supporting adherence to antitubercular treatment in South India

**Scientific Title:** A randomized controlled trial of video based directly observed treatment (vDOT) via mobile phones and conventional DOT for tuberculosis in South India

**Name of Researchers**

Dr. Rashmi Rodrigues, St Johns Hospital, Tel No: 4946 6133, Mobile No: 9845389538  
Dr. George D’souza, Chest Medicine, St Johns Hospital, Tel No: 2206 5802

*I voluntarily agree to take part in this study.*

*I have been informed, in oral and written form, about the study plan and the procedures that I will undergo as part of this study. The possible harms and discomforts and the possible benefits of this study have been explained to me. All my questions have been answered. I am aware that I can withdraw at any time and for any reason from this study.*

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<th>Name of Participant</th>
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*Name of person obtaining consent*

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*Name of the investigator*

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<td><strong>Date of the informed consent discussion</strong></td>
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<td><strong>Name of the researcher administering the informed consent &amp; this cover sheet</strong></td>
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<td><strong>Was informed consent obtained prior to the study procedure?</strong></td>
<td>Yes / No</td>
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<td><strong>Was the participant able to read?</strong></td>
<td>Yes / No</td>
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<td><strong>In what language was informed consent obtained?</strong></td>
<td>□ Kannada □ Hindi □ Tamil □ English □ Telugu</td>
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<td><strong>Did the participant accept the copy of the informed consent?</strong></td>
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<td><strong>Reasons for agreeing to participate:</strong></td>
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**Informed consent cover sheet – to be filed in the clinic**